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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,271	09/15/2005	Jan K. Ohrstrom	7100.204-US	4949

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NOVO NORDISK, INC.  
PATENT DEPARTMENT  
100 COLLEGE ROAD WEST  
PRINCETON, NJ 08540

EXAMINER
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SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,271	<b>Applicant(s)</b> OHRSTROM, JAN K.	
	<b>Examiner</b> Phyllis G. Spivack	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4-28-05</u> . | 6) <input type="checkbox"/> Other: ____.  |

An Information Disclosure Statement filed April 28, 2005 is acknowledged and has been reviewed.

Claims 1-13 are presented and represent all of the claims under consideration.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al., Seminars in Thrombosis and Hemostasis, and Musch et al., Aliment. Pharmacol. Ther., in view of Nielsen et al., Cytokines, Cellular and Molecular Therapy.

Lorenz teaches the administration of factor XIII to human patients in the treatment of chronic inflammatory bowel diseases, such as ulcerative colitis and Crohn's disease. See Figure 1, page 452. Musch teaches the administration of interferon- $\beta$  to human patients in the treatment of chronic inflammatory bowel diseases, such as ulcerative colitis and Crohn's disease. Nielsen provides motivation to administer interferon- $\beta$  in conjunction with factor XIII. See Conclusions on page 274 where Nielsen teaches a multi-factorial approach towards the inhibition of immunoinflammatory reactions including non-, pro- or/and anticytokine treatment regimens. Interferon- $\beta$ , which has been used successfully in many therapeutic trials, does not interfere with the arachidonic and leukotriene B<sub>4</sub> metabolisms of the intestinal mucosa and thus appears to provide an advantage over other immunomodulators. Nielsen teaches the 'classic

Art Unit: 1614

therapy' for inflammatory bowel disease to include glucocorticoids, sulfasalazine, mesalazine, azathioprine, 6-mercaptopurine, cyclosporine and methotrexate, which are among the required drugs of claim 5.

One having ordinary skill in the gastroenterology art would have been motivated to administer interferon beta in conjunction with factor XIII in view of the combined teachings of Lorenz, Musch and Nielsen. Such would have been obvious in the absence of evidence to the contrary because it is generally *prima facie* obvious to use in combination two or more agents that have previously been used separately for the same purpose. *In re Kerkhoven*, 205 USPQ 1069 (CCPA).

Obviousness does not require absolute predictability but only a reasonable expectation of success. Specific statements in the references that would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involve not only what references expressly teach, but also what they would collectively suggest to one of ordinary skill in the art. *In re Burckel* 201 USPQ 67 (CCPA).

The selection of an optimal dosing regimen, as required by claims 9-11, optimal modes of administration, as required by claims 12 and 13, and optimal subsets of interferon beta-1, as required by claims 6 and 7, are parameters that are well within the purview of those skilled in the art through no more than routine experimentation.

No unexpected results are noted in Applicant's disclosure.

No claim is allowed.

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 23, 2006

  
Phyllis G. Spivack

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**